

**YU SHEN TANG CHINESE HERBAL MEDICINE, LLC.**

8855 E. Valley Blvd, #B1, Rosemead, CA 91770 Tel: 626-286-0171 Fax: 626-286-0172

Office of Special Nutritionals (HFX-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

SEP 20 2004

September 6, 2004

**Notification Letter for Statement on  
Dietary Supplement**

Dear FDA officers:

I am the president of Yu Shen Tang Chinese Herbal Medicine, LLC, who is, among other things, a manufacturer and distributor of dietary supplements in California. I am writing as per Code of Federal Regulations, Volume 21, Part 101.93, to notify you that we have included statements on the label and in the labeling of one of our products. The following are the information required in this notification letter:

1 Statement of Purpose:

~This is a letter to provide notification of a statement of nutritional support, including the exact wording that appears on the label and labeling for a dietary supplement.

2 Vendor Information:

Name, address, telephone and fax numbers of the manufacturer and distributor for mailing and other communication purposes, are as follows:

YU SHEN TANG CHINESE HERBAL MEDICINE, LLC.  
8855 E. Valley Blvd #B1  
Rosemead, CA 91770  
Tel. 626-286-0171  
Fax: 626-286-0172

89599

3. Product Identification:

The trade name of the product:

97S 0162

LET

14623

## Health and Tonic Capsules

The common and usual name of the product:

Hui Tian Yang Shen

A label copy showing all information displayed and provided to consumers is attached

### 4 The text of the Structure/Function Statement.

**Dietary Supplement in support of general health and improving the immune system\***

### 5 Ingredient Statement

This product is a proprietary blend of herbal and other natural ingredients. The following is a complete list of dietary ingredients:

The ingredients are listed in the order of Common Name, Scientific Name in Brackets, Part used, Traditional Chinese Medicine Name in phonetic alphabet.

Cinnamon (*Cinnamomum cassia*) twig (Gui Zhi)  
Astragalus (*Astragalus membranaceus*) root (Huang Qi)  
Salvia (*Salvia miltiorrhiza*) root (Dan Shen)  
Eucommia (*Eucommia ulmoides*) bark (Du Zhong)  
Pubescent angelica (*Angelica pubescens*) root (Du Huo)  
Notopterygium (*Notopterygium incisum*) root (Qiang Huo)  
Large -leaf gentian (*Gentiana macrophylla*) root (Qin Jiu)  
Chinese Quince (*Chaenomeles lagenaria*) fruit (Mu Gua)  
Cyathula (*Cyathula officinalis*) root (Chuan Niu Xi)  
Psoralea (*Psoralea corylifolia*) fruit (Bu Gu Zhi)  
Spatholobus (*Millettia reticulata*) stem (Ji Xue Teng)  
Eagle wood (*Aquilaria agallocha*) wood (Chen Xiang)  
Chuanxiong (*Ligusticum wallichii*) rhizome (Chuan Xiong)  
Tetrandra (*Stephania tetrandra*) root (Fang Ji)  
Ginseng (*Panax Ginseng*) root (Ren Shen)  
Safflower (*Carthamus tinctorius*) flower (Hong Hua)  
Kudzu vine (*Pueraria lobata*) root (Ge Gen)  
Dogwood (*Comus officinalis*) fruit (Shan Zhu Yu)  
Clove (*Syzygium aromaticum*) flower bud (Ding Xiang)  
Prepared Rehmannia (*Rehmannia glutinosa*) root (Shu Di Huang)  
Chinese Angelica (*Angelica senensis*) root (Dang Gui)  
Wolfberry (*Lycium barbarum*) fruit (Gou Qi Zi)  
Chinese Yam (*Dioscorea opposita*) rhizome (Shan Yao)

Cardamon (*Amomum villosum*) fruit (Sha Ren)  
Cluster (*Amomum cardamomum*) fruit (Bai Kou)

6. Suggested use: Four capsules (2 g) per dose, twice daily.

**Caution:** If taking prescription medication, consult your health professionals before use. Store at a dry place below 86° F ( 30° C), Keep this product and all drugs out of reach of children.

- 7 Statement of Affirmation:

We, as manufacture and distributor of the above mentioned product, affirm that we have substantiation that the structure/function statement (as shown in No. 4 above) made under 403(6)(r) of the federal Food, Drug and Cosmetic Act is truthful, not misleading, and scientifically valid and that the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the label or labeling

8. Disclaimer:

At the end of each structure/function statement, there is an asterisk that refers to another asterisk placed adjacent to the disclaimer. The disclaimer is placed at the bottom of the same panel or, in adjacent with the structure/function statement. The disclaimer reads

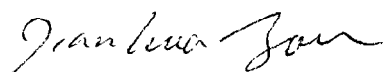
**This statement has not been evaluated by the Food and Drug Administration.  
This product is not intended to diagnose, treat, cure, or prevent any disease.**

Should there be any question or comment, please contact the Vendor through the information in No. 2 above, or contact the preparer of this notification letter:

George Su  
Crosslinks International, Inc.  
1800 Century Park East, Suite 600  
Los Angeles, CA 90067

Tel: (310)229-5748  
Fax (310)388-1067  
E-mail: [crosslinks2000@aol.com](mailto:crosslinks2000@aol.com)

Sincerely,



Zou Jianhua

President

Enclosures

## **Information on Label**

### **Healthy and Tonic Capsules**

**Dietary Supplement in support of general health and improving the immune system\***

**Net Content: 500 mg x 60 capsules**

**This product is intended to be used for persons over the age of 18**

**Suggested Use: Four capsules (2 g) per dose, twice daily.**

**Do not use if imprinted seal is broken or missing.**

**Caution: If taking prescription medication, consult your health professionals before use. Store at a dry place below 86<sup>0</sup> F ( 30<sup>0</sup> C), Keep this product and all drugs out of reach of children.**

**Expiration Date:**

**Manufactured by:  
Yu Shen Tang Chinese Herbal Medicine, LLC  
8855 E. Valley Blvd. #B1, Rosemead, CA 91770**

**Product of the USA**

**\* This statement has not been evaluated by Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

## Supplement Facts

Serving Size 4 capsules (2 g)

Servings per box 15

Amount per Serving	% Daily Value*
--------------------	----------------

**Calories, Total 5**

<b>Total Carbohydrate 0 g</b>	<b>0%</b>
-------------------------------	-----------

### Proprietary Blend (2 g)

Cinnamon ( <i>Cinnamomum cassia</i> ) twig (Gui Zhi)	†
Astragalus ( <i>Astragalus membranaceus</i> ) root (Huang Qi)	†
Salvia ( <i>Salvia miltiorrhiza</i> ) root (Dan Shen)	†
Eucommia ( <i>Eucommia ulmoides</i> ) bark (Du Zhong)	†
Pubescent angelica ( <i>Angelica pubescens</i> ) root (Du Huo)	†
Notopterygium ( <i>Notopterygium incisum</i> ) root (Qiang Huo)	†
Large-leaf gentian ( <i>Gentiana macrophylla</i> ) root (Qin Jiu)	†
Chinese Quince ( <i>Chaenomeles lagenaria</i> ) fruit (Mu Gua)	†
Cyathula ( <i>Cyathula officinalis</i> ) root (Chuan Niu Xi)	†
Psoralea ( <i>Psoralea corylifolia</i> ) fruit (Bu Gu Zhi)	†
Spatholobus ( <i>Millettia reticulata</i> ) stem (Ji Xue Teng)	†
Eagle wood ( <i>Aquilaria agallocha</i> ) wood (Chen Xiang)	†
Chuanxiong ( <i>Ligusticum wallichii</i> ) rhizome (Chuan Xiong)	†
Tetrandra ( <i>Stephania tetrandra</i> ) root (Fang Ji)	†
Ginseng ( <i>Panax Ginseng</i> ) root (Ren Shen)	†
Safflower ( <i>Carthamus tinctorius</i> ) flower (Hong Hua)	†
Kudzu vine ( <i>Pueraria lobata</i> ) root (Ge Gen)	†
Dogwood ( <i>Comus officinalis</i> ) fruit (Shan Zhu Yu)	†
Clove ( <i>Syzygium aromaticum</i> ) flower bud (Ding Xiang)	†
Prepared Rehmannia ( <i>Rehmannia glutinosa</i> ) root (Shu Di Huang)	†
Chinese Angelica ( <i>Angelica senensis</i> ) root (Dang Gui)	†
Wolfberry ( <i>Lycium barbarum</i> ) fruit (Gou Qi Zi)	†
Chinese Yam ( <i>Dioscorea opposita</i> ) rhizome (Shan Yao)	†
Cardamon ( <i>Amomum villosum</i> ) fruit (Sha Ren)	†
Cluster ( <i>Amomum cardamomum</i> ) fruit (Bai Kou)	†

\*Percent Daily Values are based on a 2,000 calorie diet

† Daily Value not established

Label No.: 1081906

Client No.: C07

Product: Health and Tonic Capsules (60 x 500 mg)